

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1312PAL-PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/IL2004/000733	International filing date (<i>day/month/year</i>) 06 August 2004 (06.08.2004)	Priority date (<i>day/month/year</i>) 06 August 2003 (06.08.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant TRIG MEDICAL LTD.			

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 10 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 35%;">Box No. I</td> <td style="width: 50%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input checked="" type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	<table style="width: 100%; border: none;"> <tr> <td style="width: 100%;">Date of issuance of this report 06 February 2006 (06.02.2006)</td> </tr> <tr> <td>Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Simin Baharlou</div></td> </tr> <tr> <td>Telephone No. +41 22 338 71 30</td> </tr> </table>	Date of issuance of this report 06 February 2006 (06.02.2006)	Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Simin Baharlou</div>	Telephone No. +41 22 338 71 30
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Telephone No. +41 22 338 71 30				

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 11 MAR 2005

WIPO PCT

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IL2004/000733

International filing date (day/month/year)
06.08.2004

Priority date (day/month/year)
06.08.2003

International Patent Classification (IPC) or both national classification and IPC
G06T7/60, A61B5/107, A61B8/08

Applicant
TRIG MEDICAL LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000733

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000733

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000733

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 1, 2, 9, 10, 12-14

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 1, 2, 9, 10, 12-14
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2004/000733

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 3-8

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	5-8
	No: Claims	3,4
Inventive step (IS)	Yes: Claims	
	No: Claims	5-8
Industrial applicability (IA)	Yes: Claims	3-8
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- 1** **Claims 1, 2, 9, 10 and 12-14** relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. The presently claimed methods include the steps of touching the position sensors to a fetal head and/or to the mothers cervix. Claims 9,10 and 12-14 do not explicitly mention the positioning of these sensors, but according to the description of the present application, 3D positional data are collected from position sensor located inside the body. These method steps represent implicitly a surgical intervention (positioning of the sensors) on a living subject which has to be carried out by a medical practitioner. Therefore these methods are regarded to be methods for treatment of the human or animal body by surgery. Consequently, no opinion will be formulated of the subject-matter of these claims (Article 34(4)(a)(I) PCT)

Re Item IV

Lack of unity of invention

- 2** This Authority considers that there are **3 inventions** covered by the claims indicated as follows:
- I: Claims 3-8 directed to a method for identifying fetal head contour in an ultrasound image;
- II: Claim 11 directed to a method for mapping body parts outside of a pelvic region by external sensors
- III: Claims 15-27 directed to constructional details of an apparatus comprising a position sensor assembled with a sleeve;
- 2.1** Document US-2003/0114779 (D6) is considered to be the prior art. The difference between the disclosure of D6 and the three inventions can be defined as follows:
- Claims 3-8: The difference between the subject matter of these claims and D6 is the use of an elliptic mask to find the fetal head contour in an ultrasound image. The problem to be solved is to improve the imaging algorithm for more accurate

determination of BPD of the fetal head and orientation of BPB inside the mothers pelvic inlet.

Claim 11: This claim deals with enhanced mapping of body parts by extrapolation and model stretching. The problem to be solved is to increase accuracy of pelvimetry.

Claims 15-27: This invention covers an apparatus comprising position sensors assembled with a sleeve. The problem to be solved is to improve the construction of the position sensors to reduce the mothers and fetal risk (e.g injury, contamination and infection) during the examination.

Since the above mentioned special technical features (STF) of the independent claims on file (i.e. elliptic mask, model stretching and sleeve), which make a contribution over the prior art, are neither identical nor corresponding, there are no same or corresponding STF shared by all independent claims of the invention. In conclusion, therefore the 3 groups of claims are not linked by a common or corresponding STF and define 3 different inventions not linked by a single general inventive concept. The application, hence does not meet the requirement of Unity of Invention as defined in **Rules 13.1, 13.2 PCT**.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3 Reference is made to the following documents:

- D1: US-A-5 605 155 (KIM YONGMIN ET AL) 25 February 1997 (1997-02-25)
- D2: US-B-6 375 6161 (BERMAN MICHAEL ET AL) 23 April 2002 (2002-04-23)
- D3: US-A-5 185 809 (KENNEDY DAVID N ET AL) 9 February 1993 (1993-02-09)
- D4: US-A-5 588 435 (GUECK WAYNE ET AL) 31 December 1996 (1996-12-31)
- D5: US-A-5 838 592 (SPRATT RAY STEVEN) 17 November 1998 (1998-11-17)
- D6: US 2003/114779 A1 (PALTIELI YOAV) 19 June 2003 (2003-06-19)

- 4 The present application does **not meet the criteria of Article 33(1) PCT**, because the subject-matter of **claim 3 and 4 is not new** in the sense of **Article 33(2) PCT**.

- 4.1 Document D1 discloses (the references in parentheses applying to this document):

A method for identifying a BPD pattern in an ultrasound image, the method comprising:

identifying an effective ultrasound beam area (col. 5, lines 35-42);
identifying a fetal head contour within the EUB area (col. 5, lines 44-56); and
identifying a BPD signature within the fetal head contour (col. 9, lines 4-27).

The subject-matter of **claim 3** is therefore **not novel (Article 33(2) PCT)**.

- 4.2 Furthermore D1 discloses, that the fetal head contour is found by using an ellipse mask (col. 9, lines 8-10; claim 8). Therefore **dependent claim 4** is also not novel (**Article 33(2) PCT**).

- 5 The subject-matter of **claim 5** does **not involve an inventive step** in the sense of **Article 33(3) PCT**.

- 5.1 Document **D2** is regarded as being the closest prior art to the subject-matter of claim 5, and discloses the following features:

approximating fetal head by a an ellipsoid (col. 11, lines 30-36);
identifying head voxels in 2D ultrasound images and defining a stable head ellipsoid (Fig. 7; col. 7, lines 6-24);

- 5.2 The distinguishing feature between the disclosure of D1 and present claim 5 is that the orientation of the BPD is determined by using the asymmetry of the fetal head voxels.

- 5.3 However, this distinguishing method step has already been employed for the same purpose in a similar method, see document D3, col. 4, lines 26-38. The distortion of hemispheric symmetry of a head is used to determine location and orientation of anatomic features (e.g. nose of a fetal) (col. 3, lines 8-25); It would be obvious to the person skilled in the art, namely when the same result is to be

achieved, to apply this method step with corresponding effect to an ultrasound imaging method according to document D1, thereby arriving at a method according to claim 1. The subject-matter of claim 1 does therefore not involve an inventive step (Article 33(3) PCT).

- 5.4 The features of dependent claims 6-8, are also known from D2 or D3. Consequently, the subject-matter of **dependent claims 6-8 lack also an inventive step (Article 33 (3) PCT).**